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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Mai H. Nguyen	Examiner:	Natalie A. Davis
Serial No.:	09/901,339	Group Art Unit:	1642
Filed:	July 9, 2001	Docket:	30448.73USU1
Title:	METHOD OF DIAGNOSING BREAST CANCER USING NIPPLE FLUID		

CERTIFICATE UNDER 37 CFR 1.8
I hereby certify that this paper or fee is being deposited with the United States Postal as first class mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231 on June 7, 2002.

By: _____
Name: Tracy Truick

35 N. Arroyo Parkway, Suite 60
Pasadena, California 91103
June 7, 2002

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

COPY OF PAPERS ORIGINALLY FILED

We are transmitting herewith the attached:

- ☒ Transmittal sheet, in duplicate, containing Certificate under 37 CFR 1.8.
- ☒ Response To The Office Action Of May 7, 2002
- ☒ Return postcard

Please charge any additional fees or credit overpayment to Deposit Account No. 50-0306. A duplicate of this sheet is enclosed.

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Dkt. 30448.73USU1 SLM/RDG

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Mai H. Nguyen

Serial No.: 09/901,339 Examiner: Natalie A. Davis

Filed: July 9, 2001 Group Art Unit: 1642

For: METHOD OF DIAGNOSING BREAST CANCER USING NIPPLE FLUID

#86 6-29-02

35 North Arroyo Parkway
Pasadena, California 91103
June 7, 2002

Honorable Assistant Commissioner for Patents
Washington, D.C. 20231

Madam/Sir:

RESPONSE TO THE OFFICE ACTION OF MAY 7, 2002

This Response is being submitted to the Office Action dated May 7, 2002, issued by the U.S. Patent and Trademark Office in connection with the above-identified application. A response to the Office Action is due June 7, 2002. Accordingly, this Response is being timely filed.

RESTRICTION REQUIREMENT

In the Office Action, the Patent Office is requiring restriction under 35 U.S.C. §121 to one of the following Groups of inventions:

Group I: Claims 1-7 are drawn to a method of diagnosing breast cancer, classified in class 435, subclass 7.1;

Group II: Claim 8 is drawn to a method of determining the progress of breast cancer, classified in class 435, subclass 4; and

Group III: Claims 9-11 are drawn to a diagnostic kit for detecting breast cancer, classified in class 530, subclass 387.1.

TRAVERSAL

Applicants hereby confirm election of the invention of Group I with traverse.

The Patent Office alleges that the inventions of Groups I-III are distinct from one another. Applicants request reconsideration of the Restriction Requirement for the following reasons:

Applicants point out that under MPEP §803, there are two criteria for proper restriction, namely: (1) the invention must be independent and distinct; AND (2) there must be serious burden on the Examiner for restriction to be required.

Applicants respectfully contend that the first requirement of §803 has not been met, since the claimed methods in Group I and II are related. The Patent Office asserts that the inventions in Groups I and II require different modes of operation, different reagents and serve different endpoints and effects. Applicants contend that the methods claimed in Group I and II are related because they both involve measuring basic fibroblast growth factor (bFGF) in a test sample of nipple fluid. Therefore, the invention in Groups I and II are not independent.

The Patent Office states that the inventions in Groups III and I -II are related as product and process of use. The Patent Office also states that the diagnostic kit of Group III can be used to screen for bFGF antagonist and/or agonists. Applicants contend that the diagnostic kits of Group III can be used to perform the methods of Groups I and II (i.e., methods for diagnosing breast cancer or a high risk of breast cancer, or methods for determining the progress of breast cancer). The claimed kits contain reagents and instructions for carrying out these methods rather than methods for screening for bFGF antagonists and/or agonists. Therefore, the invention in Groups I –II and III are not independent. Accordingly, the criteria for requiring restriction have not been met.

Applicants respectfully contend that the second requirement of §803 has also not been met. The Patent Office has not demonstrated a serious burden for searching the art. In fact, Group I and II are classified in class 435. The fact that the claims of Groups I-II are in the same class, indicate that a search of the art would not place an undue burden on the Examiner. Additionally, a search of the methods of Group I or II would be likely to overlap with the art uncovered in a search of art relevant to the kits of Group III. Moreover, separate prosecution of these claims would be unnecessarily duplicative and thus wasteful of Patent Office resources. Therefore, under MPEP § 803, the instant claims do not require restriction.

Thus, the Examiner can perform a search on the entire application without serious burden. Moreover, separate prosecution of these claims would be unnecessarily duplicative and thus wasteful of Patent Office resources. Therefore, under MPEP Section 803, the instant claims do not require restriction.

Applicants respectfully request that the Examiner reconsider and withdraw the Restriction Requirement as these claims.

Conclusion

No fee is deemed necessary in connection with the filing of this Amendment. If any fee is necessary, the Patent Office is authorized to charge any additional fee to Deposit Account No. 50-0306.

Respectfully submitted,

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